REMARKS

Entry of the above amendments and reconsideration of this application are requested. In view of the amendments and the following remarks, it is believed that all rejections have been overcome and that this application is in condition for allowance.

Status of All of the Claims

Upon entry of the amendments, the status of the claims in the application will be as follows:

1. Claims 27-54 and 64-67 will be pending and under consideration.
2. Claims 1-26 and 55-63 will have been cancelled.

IDS

A supplemental IDS is being filed with this Response. It is meant to replace and add to the IDS filed on August 17, 2007, which was deemed defective by the Examiner.

Claim Rejections – 35 U.S.C. § 112

Claims 50-54 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant respectfully disagrees.

It is understood by those skilled in the art that the term "peroxy compound" is a generic term representing a class of compounds containing a peroxy group (—O—O—). It is also understood that peracids, because they contain one or more peroxy groups, are members of this class, thus providing the genus-species relationship presently claimed. This relationship is

supported throughout the original disclosure, for example, in the text spanning pages 11-14 of the application, and more specifically at page 11, lines 22-24.

Hawley's Condensed Chemical Dictionary, which was cited by the Examiner in the previous Office Action, corroborates these definitions. It is known that the term "peroxy" is often shortened to "per-", which Hawley's defines as "... specifically denoting (2) presence of the peroxy group, —O—O—, ..." (See Hawley's p. 886). Thus, it is inherent that the term "peroxy compound" means a compound containing a peroxy group. Hawley's recognizes that peracids contain a peroxy group. It states that peracid molecules "contain one or more directly linked pairs of oxygen atoms, —O—O—. (See Hawley's definition of "peracids" on p. 886). Thus, a "peracid" is a species of the genus "peroxy compounds". Withdrawal of these rejections is thus solicited.

Claim Rejections – 35 U.S.C. § 102

Claims 45 and 46 stand rejected under 35 U.S.C. §102(b) as being anticipated by Badylak et al., U.S. Patent No. 4,902,508. Claim 45 has been amended to modify the "removing" step. It now recites "removing the collagen-based matrix from said treated submucosa tissue source." The Badylak '508 reference does not teach the subject matter of claim 45. Claim 46, being dependent upon claim 45, also is not anticipated by the Badylak '508 reference for at least this reason. Withdrawal of these rejections is thus solicited.

Claims 45-54 stand rejected under 35 U.S.C. §102(e) as being anticipated by Badylak et al., U.S. Patent No. 5,695,998. Claim 45 has been amended to modify the "removing" step as noted above. The Badylak '998 reference does not teach the subject matter of claim 45. Claims

46-54, being dependent upon claim 45, also are not anticipated by the Badylak '998 reference for at least this reason. Withdrawal of these rejections is thus solicited.

Claim Rejections – 35 U.S.C. § 103

Claims 27-44 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Badylak et al., U.S. Patent No. 5,695,998 in view of O'Leary, U.S. Patent No. 5,298, 222 or Kemp, U.S. Patent No. 5,460,962.

The Examiner contends that the Badylak '998 reference teaches the whole subject matter of claim 27 except for the order in which the "treating" and "removing" steps are carried out, and that either Kemp or O'Leary provides this missing limitation. Applicant respectfully disagrees.

Example 3 is exemplary of all that Kemp teaches. (See Column 4, line 61 extending over to Column 5, line 31). Prior to any treatment with a disinfecting agent, the small intestine of Kemp is "trimmed into a sheet, mechanically stripped and cleaned so that the tunica submucosa is [was] delaminated and separated." Subsequently, the delaminated intestinal material is "immersed in 100 ml of neutral, 0.1% peracetic acid solution." There is no suggestion whatsoever to contact the intestinal tissue of Kemp with a disinfecting agent before the trimming, mechanical stripping, etc.

Clearly, Kemp does not provide the missing limitation that would have taught or suggested modification of the Badylak '998 process to arrive at the invention of claim 27. In fact, Kemp would have directed the skilled artisan squarely away from the subject matter of claim 27, because it only would have suggested treating the tissue source of Badylak with a disinfecting agent after the delamination step of Badylak. In this way, Kemp endorses what Badylak already teaches.

O'Leary also does not provide the missing limitation that would have taught or suggested modification of the Badylak '998 process to arrive at the invention of claim 27. O'Leary stresses the importance of carrying out its process under sterile conditions. While providing a sterile environment is often an important part of a tissue graft preparation process, the distinction must be made between carrying out a process under sterile conditions, and treating something with a disinfecting agent as claimed.

The musculoskeletal tissue of O'Leary is indeed processed under sterile conditions. However, it undergoes considerable mechanical processing prior to being treated with a disinfecting agent. O'Leary's main embodiment involves bone. During processing, connective tissue and periosteum are removed from the bone, and the bone is shaped into a specific size. Only later is the bone treated with a disinfectant. Thus, O'Leary does not provide the missing limitation that would have taught or suggested modification of the Badylak '998 process to arrive at the invention of claim 27. In fact, O'Leary would have directed the skilled artisan squarely away from the subject matter of claim 27, because, if anything, it would have suggested treating the tissue source of Badylak with a disinfecting agent after the delamination step of Badylak. In this way, O'Leary—like Kemp—endorses what Badylak already teaches. For at least these reasons, claim 27 is not rendered obvious by Badylak '998 in view of O'Leary or Kemp. Claims 28-44, being dependent upon claim 27, also are not rendered obvious by the cited art for at least these reasons.

Claims 64 - 67

Support for the subject matter of claims 64 – 67 can be found throughout the original disclosure. For example, at page 15, lines 9-13 of the filed application, it teaches to provide a

submucosa tissue source that includes submucosa tissue and tunica muscularis tissue that is attached to the submucosa tissue, and that some methods of the present invention include separating submucosa tissue from attached tunica muscularis tissue. Treating submucosa tissue with a disinfecting agent (e.g., peracetic acid) is discussed, for example, at page 11, lines 19-24 of the application, but also generally in the text spanning pages 11-15 and elsewhere throughout the original disclosure. Recovering a collagen-containing matrix including submucosa tissue is discussed numerous times throughout the original disclosure including, for example, at page 4, line 26 of the application. Obtaining a collagen-containing matrix that has at least submucosa tissue and lamina propria tissue is discussed at page 5, line 16 of the application. Obtaining a matrix exhibiting an endotoxin level of less than 1 endotoxin unit per gram is taught in the original disclosure including, for example, at page 7, line 5 and page 17, lines 19-21 of the application. Obtaining a matrix exhibiting a bioburden of less than 0.5 colony forming units per gram is taught in the original disclosure including, for example, in TABLE 1 at page 17 of the application. Obtaining a matrix retaining basic fibroblast growth factor from the tissue source is taught, for example, at page 16, line 26 of the application. Obtaining a matrix exhibiting the capacity to induce angiogenesis is taught, for example, at page 16, line 21 of the application. Porcine tissue sources (claim 66) are disclosed at page 9, line 22. Urinary tract tissue sources (claim 67) are disclosed at page 9, line 26.

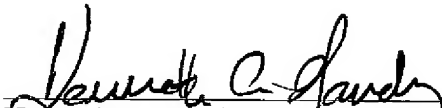
None of the cited references (Badylak '508, Badylak '998, O'Leary or Kemp) alone or in combination teach or suggest the subject matter of claims 64-67. The processes described in those references simply would not have taught the skilled artisan a method as claimed to obtain the type and character of collagen-containing matrix recited in claims 64-67.

It is believed that the above amendments and the following remarks address all outstanding rejections. Allowance of the application is thus solicited.

Request for Interview

In the event that the Examiner finds any reason that the application cannot be allowed in its present form, the Applicant wishes to conduct an interview with the Examiner prior to any next Office Action in order to provide an opportunity to come to an agreement on acceptable claim language. To arrange the interview, the Examiner should call the undersigned attorney at the telephone number given.

Respectfully submitted,

By 

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